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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/796,441

03/08/2004

Michael Radomsky

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22434 7590 06/25/2008
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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/796,441	Applicant(s) RADOMSKY, MICHAEL	
	Examiner MICHAEL C. HENRY	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/28/07 & 04/21/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/07/08 has been entered.

The following office action is a responsive to the Amendment filed, 05/07/08.

The amendment filed 05/07/08 affects the application, 10/796,441 as follows:

Claims 17-20 have been canceled. Claim 21 has been amended. Upon further consideration, it was determined that the indication of allowable subject matter in the prior office action mailed 04/09/07 was not appropriate. Consequently, the said allowable subject matter is withdrawn. A new ground(s) rejection is made herein.

1. The responsive to applicants' amendment is contained herein below.

Claims 21-22 are pending in application

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke et al. (WO 9409722).

In claim 21, applicant claims “A method of treating diseased, injured or abnormal bone at a site of desired bone growth comprising the step of applying to said site a composition comprising an effective amount of a mixture of hyaluronic acid, growth factor bFGF and excipients to maintain biological activity of said factor, said composition being sufficient to enhance bone growth rate and magnitude and having a viscosity and biodegradability sufficient to persist at said site for a period of time sufficient to enhance said bone growth rate and magnitude.” Claim 22 is drawn to a method according to claim 21 wherein said bFGF is present in a range of about 10^{-6} to 100 mg/ml in said composition.

Brekke et al. disclose a composition for treating bone such as abnormal bone at a site of desired bone growth (e.g., the voids in bone) comprising the step of applying to said site a composition comprising a mixture of hyaluronic acid, growth factor bFGF and excipients, and wherein the said composition can promote (enhance) bone growth (see abstract, page 4, line 20 to page 7, line 11 and especially page 6 the paragraph numbered as 4; also see claims)

The difference between applicant's claimed method and the method taught by Brekke et al. is that Brekke et al. does not exemplify the use of said composition, per se.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Brekke et al. to treat abnormal, injured or diseased bone by applying to the site of said abnormal, injured or diseased bone a composition comprising an effective amount of a mixture of hyaluronic acid, a growth factor and excipients and to alter the viscosity of said composition depending on factors such as the severity of the bone condition or disorder and the individual that is being treated.

One having ordinary skill in the art would have been motivated to use the method suggested by Brekke et al. to treat abnormal, injured or diseased bone by applying to the site of said abnormal, injured or diseased bone a composition comprising an effective amount of a mixture of hyaluronic acid, a growth factor and excipients and to alter the viscosity of said composition depending on factors such as the severity of the bone disease and the individual that is being treated. It should also be noted that use of specific concentration of the components (such as bFGF) of said composition also depending on factors such as the severity of the bone condition or disorder and the individual that is being treated.

Response to Arguments

Applicant's arguments with respect to claims 21-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

June 14, 2008.

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623